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10/523,019	02/02/2005	Kazuhiro Iida	8022-1087	6535

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EXAMINER	
MUI, CHRISTINE T	
ART UNIT	**PAPER NUMBER**
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,019	IIDA, KAZUHIRO	
	Examiner	Art Unit	
	Christine T. Mui	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-63,68,69,71-74 and 76-82* is/are rejected.

7)☒ Claim(s) *64-67,70 and 75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02 February 2005; 02 May 2005; 07 May 2007; 31 March 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 64 recites the limitation "catcher" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 41-42, 45-47, 50-55, 58-62, 71-74, 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/03104 to Lackie (herein referred 'Lackie'), and further in view of JP 60-241004 to Akira et al (herein referred 'Akira').

4. Regarding claim 41-42, the reference Lackie discloses a system for assaying a fluid sample with an optical system. The optical system includes a flow cell that includes a focusing lens characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising of a tubular passage. The fluid in the cell can be excited into emission such as fluorescence (see page 3, lines 12-14, page 4, lines 18-33; Figure 1-3). Lackie does not disclose a scale placed along side of the sensing element. Akira discloses a particle analyzer that enables the measurement of flow diameter of a sample liquid, by including a flow diameter measuring means for measuring the flow diameter of the sample liquid irradiated with light from a light source for measuring flow diameter regardless of the concentration of the sample (see abstract). It is interpreted by the examiner that from the figure in the patent abstract, the measuring means is placed along a device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensing element with a scale along side of the element to provide a guide or key or a measuring means for determine the progress of the reactions.

5. Regarding claim 45, the references Lackie and Akira disclose the claimed invention. Lackie discloses the lens is characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising a

tubular passage, typically of circular cross section (see page 4, lines 23-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape and angle of the bottom surface of the flow channel in which the fluid flow through the device as it just a change in shape of the channel but provides the same function of allowing the passage of fluids.

6. Regarding claim 46, the references Lackie and Akira disclose the claimed invention. Lackie discloses an optical system including a light source providing for excitation radiation and a lens that focuses the radiation onto the chamber (see page 4, lines 7-9, 28-33).

7. Regarding claim 47, the references Lackie and Akira disclose the claimed invention. Lackie discloses the system includes one or more separate porous masses of light transparent material disposed in the conduit means. The porosity of the mass of transparent material is selected to permit fluid flow of the sample there through, at least a moiety of a respective ligand/conjugate complex, on the surface of each mass. In one embodiment, the mass comprises of a plurality of particles preferably substantially transparent to light. The particles are typically beads dimensioned with a specified range of diameters and can be performed by sintering or the like (see page 2, line 31-page 3, line 5).

8. Regarding claim 50, the references Lackie and Akira disclose the claimed invention. Lackie discloses the lens is characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising a tubular passage, typically of circular cross section (see page 4, lines 23-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape and angle of the bottom surface of the flow channel in which the fluid flow through the

device as it just a change in shape of the channel but provides the same function of allowing the passage of fluids.

9. Regarding claim 51, the references Lackie and Akira disclose the claimed invention. Lackie discloses an optical system including a light source providing for excitation radiation and a lens that focuses the radiation onto the chamber (see page 4, lines 7-9, 28-33).

10. Regarding claims 52-53, the references Lackie and Akira disclose the claimed invention. Lackie discloses the system for assaying a fluid sample, typically employing a tag or label intended to emit electromagnetic radiation and when excited (see page 2, lines 27-30). It is interpreted by the examiner that when the fluid comes in contact with a bead with a specific binding ligand a reaction will occur and tagged or labeled sample can be excited. Furthermore, it is interpreted by the examiner that when a fluid is in the channel for testing, it is uniformly distributed within the device when it is place in a horizontal orientation.

11. Regarding claims 54-55, the references Lackie and Akira disclose the claimed invention. Akira discloses a particle analyzer that enables the measurement of flow diameter of a sample liquid, by including a flow diameter measuring means for measuring the flow diameter of the sample liquid irradiated with light from a light source for measuring flow diameter regardless of the concentration of the sample (see abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a scale in the form of a hue pattern along side the sensing element to gage the progress of a reaction by the color it forms as a sample and reagent come into contact with each other. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the hue

pattern scale in a groove adjacent to the channel so that upon handling of the device, the hue patter scale is not moved and remains in a place that can be observed with ease.

12. Regarding claim 58, the references Lackie and Akira disclose the claimed invention. Lackie discloses the lens is characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising a tubular passage, typically of circular cross section (see page 4, lines 23-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape and angle of the bottom surface of the flow channel in which the fluid flow through the device as it just a change in shape of the channel but provides the same function of allowing the passage of fluids.

13. Regarding claim 59, the references Lackie and Akira disclose the claimed invention. Lackie discloses an optical system including a light source providing for excitation radiation and a lens that focuses the radiation onto the chamber (see page 4, lines 7-9, 28-33).

14. Regarding claims 60-61, the references Lackie and Akira disclose the claimed invention. Lackie discloses the system for assaying a fluid sample, typically employing a tag or label intended to emit electromagnetic radiation and when excited (see page 2, lines 27-30). It is interpreted by the examiner that when the fluid comes in contact with a bead with a specific binding ligand a reaction will occur and tagged or labeled sample can be excited. Furthermore, it is interpreted by the examiner that when a fluid is in the channel for testing, it is uniformly distributed within the device when it is place in a horizontal orientation.

15. Regarding claim 62, the references Lackie and Akira disclose the claimed invention. Lackie discloses the system includes one or more separate porous masses of light transparent

material disposed in the conduit means. The porosity of the mass of transparent material is selected to permit fluid flow of the sample there through, at least a moiety of a respective ligand/conjugate complex, on the surface of each mass. In one embodiment, the mass comprises of a plurality of particles preferably substantially transparent to light. The particles are typically beads dimensioned with a specified range of diameters and can be performed by sintering or the like. The beads may also be coated with at least a moiety of the antibody/antigen complex, specific-binding ligand, for example an antigen and an antibody thereto disposed on at a portion of the surface of the bead (see page 2, line 31-page 3, line 5, page 5, line 2-6).

16. Regarding claim 71, the references Lackie and Akira disclose the claimed invention. Lackie discloses a flow cell with a hollow light transparent conduit means for fluid there through that allows the passage of a fluid sample through the flow cell that comes into contacted with a moiety of ligand/conjugate complexes (see claim 1). Lackie does not specifically discloses a solution holder and the solution that is introduced in to the flow cell flows by capillary action, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a solution holder for supplying an amount of solution into the system and to modify the dimensions of the conduit to allow the fluid to flow by capillary action so that one does not need to use alternative forms of ways to pump or move the fluid through the device.

17. Regarding claim 72, the references Lackie and Akira disclose the claimed invention. Lackie discloses a flow cell with a hollow light transparent conduit means for fluid there through that allows the passage of a fluid sample through the flow cell that comes into contacted with a moiety of ligand/conjugate complexes (see claim 1). Lackie does not specifically disclose a plurality of channels and corresponding solution holders for each of the channel, but it would

have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plurality of channel as well as solution holders so that multiple samples, solutions or reagents can be mixed and processed through the device without having to use multiple cells for testing.

18. Regarding claim 73, the references Lackie and Akira disclose the claimed invention. Lackie discloses the lens is characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising a tubular passage, typically of circular cross section. Lackie also discloses that a conduit in the device has a reflective surface for as least part of the inner surface of passage (see page 4, lines 23-26, claim 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape and angle of the bottom surface of the flow channel in which the fluid flow through the device as it just a change in shape of the channel but provides the same function of allowing the passage of fluids.

19. Regarding claim 74, the references Lackie and Akira disclose the claimed invention. Lackie discloses a channel has a reflective surface on part of the inner surface of the passage where fluid sample flows through (see claim 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surface of the channel to be made of a material that has a reflective index that is equal or less than the refractive index of water so that upon observing a reaction within the chip there is not any delay of the light reflected through the medium.

20. Regarding claim 77-80, the reference Lackie discloses a system for assaying a fluid sample with an optical system. The optical system includes a flow cell that includes a focusing

lens characterized by having an elongated hollow channel or fluid flowing conducting conduit therein directed transversely to the optical axis of the lens and comprising of a tubular passage. The fluid in the cell can be excited into emission such as fluorescence. The term light used in the invention is understood to include wavelengths in the visible spectrum as well as those in the near infrared and ultraviolet as well (see page 3, lines 12-14, page 4, lines 6-33; Figure 1-3). Lackie does not disclose a scale placed along side of the sensing element. Akira discloses a particle analyzer that measures the flow diameter of a sample liquid when it is irradiated with light from a light source for measuring the flow diameter regardless of the concentration of the sample particles.

21. Regarding claim 81, the references Lackie and Akira disclose the claimed invention except for specifically disclosing the illumination member is either a bulb, LED or a black light. It would have been obvious to one having ordinary skill in the art at the time invention was made to have an illumination member be a source such as a bulb, LED or a black light to illuminate the flow cell to excite the contents to an excitation of fluorescence, polarized or not, by radiation, excitation of chemiluminescence or emission of reflection of light from chromogens.

22. Regarding claim 82, Lackie and Akira disclose the claimed invention except for specifically disclosing the illumination member collects natural light. Lackie discloses a set up that can be see in Figure 1, that the apparatus for assaying a fluid sample that may typically employ an optical system that includes light source and lens on the flow cell, that the light that is transmitted from the light source is parallel to the surface of the flow well that the channels and lens are on. The light bends form a mirror deviating the light source path 90 degrees so that it illuminates the flow cell at 90 degrees (see Figure 1, page 4, lines6-27). It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the illumination light source member be natural light to observe the effect natural light has on the progress of a reaction.

23. Claims 43-44 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackie and Akira as applied to claim 41 above, and further in view of USP 5,498,392 to Wilding et al (herein referred 'Wilding').

24. Regarding claims 43-44, the references Lackie and Akira disclose the claimed invention except for a reagent separator. Wilding discloses a device for amplifying a pre selected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. The polynucleotide polymerization can be detected by the use of a mesoscale flow system sensitive to flow restriction, constructed with a fractal pattern. The fractally bifurcating channels may be fabricated on a silicon substrate with reduced dimensions at each bifurcation. A substrate may be fabricated with a fractally bifurcating system of flow channels connected via a channel to ports and a PCR reaction chamber (see column 12, lines 29-51; Figure 7). Furthermore, Lackie discloses a mesh or porosity of screen that is selected to allow a free flow of a sample fluid and its constitutients there through while arresting the flow of coated beads (see page 5, lines 8-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzing device to have a reagent separator with a barrier separating the fluid from particles so that fluids to be analyzed are free from beads or particles or even debris.

25. Regarding claims 68-69, the references Lackie and Akira disclose the claimed invention except for placing a polymer solution and bead in the channel changing the viscosity of the polymer. Lackie discloses a mesh or porosity screen selected to allow the free flow of sample

fluid and its constituents there through which arresting the flow of the coated beads (see page 5, lines 8-11). Wilding discloses a device for amplifying a pre-selected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. The polynucleotide polymerization can be detected by the use of a mesoscale flow system sensitive to flow restriction, constructed with a fractal pattern. The fractally bifurcating channels may be fabricated on a silicon substrate with reduced dimensions at each bifurcation. A substrate may be fabricated with a fractally bifurcating system of flow channels connected via a channel to ports and a PCR reaction chamber. The flow through the fractal is sensitive to changes in the fluid viscosity that is caused by the presence of polymerized product. Flow restriction in the fractal region can be detected through a transparent cover of the detection region. Furthermore, in an embodiment of Wilding, paramagnetic or ferromagnetic beads may be provided within the mesoscale flow system which can be moved along the flow system by an external magnetic field (see column 12, line 29-column 13, line 5, column 13, lines 62-65). It would have been obvious to one having ordinary skill in the art at the time invention was made to provide the chip with a polymer solution that changes viscosity within the channel to observe the changes in the sample in the event that it is used for subsequent reactions.

26. Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackie and Akira as applied to claim 47 above, and further in view of Wilding.

27. Regarding claims 48-49, the references Lackie and Akira disclose the claimed invention except for a reagent separator. Wilding discloses a device for amplifying a pre selected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. The polynucleotide polymerization can be detected by the use of a mesoscale flow system sensitive to

flow restriction, constructed with a fractal pattern. The fractally bifurcating channels may be fabricated on a silicon substrate with reduced dimensions at each bifurcation. A substrate may be fabricated with a fractally bifurcating system of flow channels connected via a channel to ports and a PCR reaction chamber (see column 12, lines 29-51; Figure 7). Furthermore, Lackie discloses a mesh or porosity of screen that is selected to allow a free flow of a sample fluid and its constitutients there through while arresting the flow of coated beads (see page 5, lines 8-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzing device to have a reagent separator with a barrier separating the fluid from particles so that fluids to be analyzed are free from beads or particles or even debris.

28. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackie and Akira as applied to claim 54 above, and further in view of Wilding.

29. Regarding claims 56-57, the references Lackie and Akira disclose the claimed invention except for a reagent separator. Wilding discloses a device for amplifying a pre selected polynucleotide in a sample by conducting a polynucleotide polymerization reaction. The polynucleotide polymerization can be detected by the use of a mesoscale flow system sensitive to flow restriction, constructed with a fractal pattern. The fractally bifurcating channels may be fabricated on a silicon substrate with reduced dimensions at each bifurcation. A substrate may be fabricated with a fractally bifurcating system of flow channels connected via a channel to ports and a PCR reaction chamber (see column 12, lines 29-51; Figure 7). Furthermore, Lackie discloses a mesh or porosity of screen that is selected to allow a free flow of a sample fluid and its constitutients there through while arresting the flow of coated beads (see page 5, lines 8-11). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify the analyzing device to have a reagent separator with a barrier separating the fluid from particles so that fluids to be analyzed are free from beads or particles or even debris.

30. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lackie and Akira as applied to claim 62 above, and further in view of US Publication No. 2002/0064800 to Sando et al (submitted on the Information Disclosure Statement on 31 March 2008; herein referred 'Sando').

31. Regarding claim 63, the references Lackie and Akira disclose the claimed invention except for a reactor formed on the channel. Sando discloses a microchip wherein in one of the embodiments, there is a reagent fixing unit provided in a suitable position for allowing flow to pass through the device (see [0060]). It is interpreted by the examiner that the reagent fixing unit is a reactors that allow reagents to be temporarily stored in or where reactions may take place within the device for thorough mixing. Lackie discloses a mesh or porosity screen that is selected to allow the free flow of sample fluids and its constitutients there through while arresting flow of the coated beads (see page 5, line 8-11). It would have been obvious to one having ordinary skill to provide a reactor on the channel so that there is sufficient space for mixing of reagents and samples within the flow cell.

32. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lackie and Akira and Sando as applied to claim 63 above.

33. Regarding claim 76, the references Lackie, Akira and Sando disclose the claimed invention. Lackie discloses that within the hollow light transparent conduit, there are one or more porous masses that are pre coated with specific binding ligand. The specific binding ligand forms ligand/conjugate complexes such as antibody/antigen or similar complexes and an

antibody is used to assay for the presence of an antigen specific an antibody (see page 1, lines 3-11, page 2, lines 27-35).

Allowable Subject Matter

34. Claims 64-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

35. An analysis chip that is made of a substrate with a channel disposed therein with a scale on the side of the chip, wherein the width of the channel narrows as fluid flows from a catcher to another end of a channel is not found in the prior art as well as an analysis chip with a hydro-gel layer whose volume changes as it is in contact with substance introduced into the system.

36. Claims 70 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

37. An analysis chip with electrode disposed at the ends of a channel disposed within the chip that charges beads to a predetermined pH is not found in the prior art. Furthermore, an analysis chip with a cover that includes an interference band whose position is different depending on the refractive index of the substance is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797